

PATENT COOPERATION TREATY

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From the INTERNATIONAL SEARCHING AUTHORITY

PCT

INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

REGISTERED MAIL

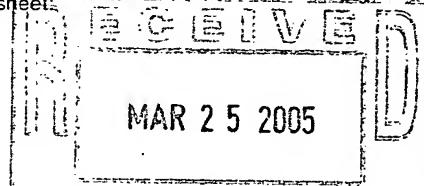
To: VENABLE, LLP Attn. Axelrod, Nancy J. P.O. Box 34385 Washington, D.C. 20043-9998 UNITED STATES OF AMERICA

Date of mailing (day/month/year)	18/03/2005
Applicant's or agent's file reference 41860-205199	PAYMENT DUE within 45 months/days from the above date of mailing
International application No. PCT/US2004/030831	International filing date (day/month/year) 21/09/2004
Applicant INTERNATIONAL LIVESTOCK RESEARCH INSTITUTE	

1. This International Searching Authority

(i) considers that there are 3 (number of) inventions claimed in the international application covered by the claims indicated below on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below on the extra sheet:



(ii) has carried out a partial international search (see Annex) will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.: see annex

(iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

2. The applicant is hereby invited, within the time limit indicated above, to pay the amount indicated below:

EUR 1.550,00 x 2 = EUR 3.100,00
Fee per additional invention number of additional inventions total amount of additional fees

Or, x =

The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. Claim(s) Nos. see annex have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Maria Brando <i>Invitation to Pay fees</i> 1 MONTH REMINDER <u>4/12/05</u> 1 MONTH REMINDER <u>4/16/05</u> 2 WEEK REMINDER <u>4/16/05</u> 3 DAY REMINDER <u>4/16/05</u> ACTION DUE AND DATE <u>5/2/05</u>
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2001 RELEASE UNDER E.O. 14176

— 10/16/85-9 78

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Euro accounts of the European Patent Organisation

Nº 3 338 800 00 (BLZ 700 800 00)

Dresdner Bank

Promenadéplatz 7

D-80273 München

SWIFT Code: DRESDEFF700

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Postbank AG

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D-80138 München

Important Information for Applicants outside Europe

general

- the claims cannot be changed at this point in the procedure, the transmitted report is not the ISR (see Art. 19 PCT)
- non-payment does not lead to a loss of rights, a new procedure will be started on entry into the regional or national phase
- any payments have to be effected directly to this ISA (account details below), payments to other entities will not be accepted
- in case of a total of more than 2 inventions found: when paying please specify exactly which claims should be searched
- an extension of the set time limit cannot be granted, as the total number of days must not exceed 45 days (Rule 40.3 PCT)

payment by cheque or money transfer:

- the date of payment is considered to be the date the money is booked in the EPO account (details on extra sheet)
- faxed cheques are not considered to be a valid payment
- only payments in EUR are accepted, no equivalents in other currencies
- payments by credit card are not possible

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note: if you don't have a deposit account with the EPO yourself you might want to consider using the account of an associate as a safe and quick way of paying

payments under protest according to Rule 40 PCT:

- the protest will not be accepted without a payment of additional search fee(s)
- the protest has to be accompanied by a technical reasoning
- no protest fee needs to be paid yet, only additional search fee(s)

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:

see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE EMBL 'Online! 2 January 2003 (2003-01-02), "EST628751 TpMugugaSh01 Theileria parva cDNA clone TPFAN22, mRNA sequence." XP002318733 retrieved from EBI accession no. EM_EST:BQ545112 Database accession no. BQ545112 the whole document</p> <p>-----</p>	17-22, 25-28, 30-33
A	<p>MCKEEVER DECLAN J ET AL: "Novel vaccines against Theileria parva: Prospects for sustainability" INTERNATIONAL JOURNAL FOR PARASITOLOGY, vol. 28, no. 5, May 1998 (1998-05), pages 693-706, XP002310753 ISSN: 0020-7519 page 702, left-hand column, last paragraph - page 703, left-hand column, paragraph 1</p> <p>-----</p>	1
A	<p>GERHARDS JOACHIM ET AL: "Sequence and expression of a 90-kilodalton heat-shock protein family member of Theileria parva" MOLECULAR AND BIOCHEMICAL PARASITOLOGY, vol. 68, no. 2, 1994, pages 235-246, XP002310752 ISSN: 0166-6851 the whole document</p> <p>-----</p> <p>-/-</p>	1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- °A° document defining the general state of the art which is not considered to be of particular relevance
- °E° earlier document but published on or after the international filing date
- °L° document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- °O° document referring to an oral disclosure, use, exhibition or other means
- °P° document published prior to the international filing date but later than the priority date claimed

- °T° later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- °X° document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- °Y° document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- °8° document member of the same patent family

Annex Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No
PCT/US2004/030831

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	MORRISON W IVAN ET AL: "Theileriosis: Progress towards vaccine development through understanding immune responses to the parasite" VETERINARY PARASITOLOGY, vol. 57, no. 1-3, 1995, pages 177-187, XP002310754 ISSN: 0304-4017 cited in the application page 184, last paragraph - page 185, paragraph 1 ----- US 5 273 744 A (NANTULYA VINAND M ET AL) 28 December 1993 (1993-12-28) cited in the application column 3, line 50 - column 4, line 4; claims 1-14 -----	1
A		1

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9, 17-21, 29-62 (all partially); 10, 13-16, 22, 25-28 (completely)

Isolated polypeptide Tp2 comprising a sequence represented by SEQ ID NO: 1 and the antigenic fragments SEQ ID NOS: 4, 5, 6 and 7, pharmaceutical or immunogenic composition or vaccine comprising said polypeptide, isolated polynucleotide comprising SEQ ID NO. 25, 28, 29, 30 or 31; pharmaceutical composition comprising said polynucleotide, vector comprising said polynucleotide, host cell comprising said vector, method of producing a polypeptide, comprising culturing said host cell, antibody specific for the polypeptide having SEQ ID NO: 1 or 4-7, kit comprising said antibody, method for protecting an animal against infection by *T. parva*, comprising administration of said polypeptide or of said host cell, method of detecting protozoan infection, method for preparing a polyclonal or monoclonal antibody against said polypeptide, method for identifying *T. parva* in a sample.

2. claims: 1-9, 17-21, 29-62 (all partially); 11, 23 (completely)

same as (1), but polypeptide Tp3 comprising a sequence represented by SEQ ID NO: 2, polynucleotide comprising SEQ ID NO: 26.

3. claims: 1-9, 17-21, 29-62 (all partially), 12, 24 (completely)

as (1), but polypeptide Tp6 comprising SEQ ID NO: 3 and polynucleotide comprising SEQ ID NO. 27.

Reasoned statement on the finding of lack of unity

The present application does not comply with the requirements of unity of invention for the following reasons:

Claim 1 is directed to 3 antigens of *Theileria parva* (Tp2, Tp3 and Tp6) and to antigenic fragments of Tp2, defined by reference to SEQ ID NOS. 1-7.

The 3 antigens show no significant structural relationship with each other.

The only single general concept which can be identified as linking the different polypeptides claimed in Claim 1 is that they are derived from *Theileria parva* and capable of inducing immunoprotection against *T. parva* by inducing a CTL response in cattle. However, this general concept is not novel, because *Theileria parva* antigens have already been disclosed in the prior art, see e.g. D1 (Gerhards et al., Mol. Biochem. Parasit. Vol. 68, pp. 235-245, 1994) which discloses the sequence of a 90 kD

heat-shock protein of *Theileria parva*. D2 (US 5273744) discloses the use of the 67 KD antigen from *Theileria parva* for inducing immunoprotection.

In view of the prior art, the different sequences referred to in claim 1 do not share a significant technical feature, which makes a contribution over the prior art. Thus, each of the different proteins in present Claim 1 provides an independent solution to the problem of providing further antigens from *Theileria parva*.

In accordance with Art. 34(3) PCT and Rule 68(2)(3) PCT the applicant is therefore invited to pay further search fees or to restrict the application to one invention. The partial International Search Report accompanying this invitation has been established on the invention first mentioned in the claims, i.e. an isolated polypeptide comprising SEQ ID NO: 1 and specific antigenic fragments thereof defined by SEQ ID NOS. 4-7.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Although claims 44-49 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Although claims 50-51 are directed to a diagnostic method that can be practised on the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Patent Family Annex

Information on patent family members

International Application No
PCT/US2004/030831

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5273744	A 28-12-1993	NONE	

Go to: General Description References Additional Cross-references Sequence

General Information

XP-002318733

Primary Accession # BQ545112
 Accession # BQ545112
 Entry Name EMBL:BQ545112
 Molecule Type mRNA
 Sequence Length 814
 Entry Division EST
 Sequence Version BQ545112.1
 Creation Date 02-JAN-2003
 Modification Date 02-JAN-2003

Description

Description EST628751 TpMugugaSh01 Theileria parva cDNA clone TPFAN22, mRNA sequence.
 Keywords EST.
 Organism Theileria parva
 Organism Classification Eukaryota; Alveolata; Apicomplexa; Piroplasmida; Theileriidae; Theileria. ;

References

1. Nene,V.; Shallom,S.; Chadha,N.; Awino,E.; Gardner,M.;
Expressed sequence tags from the schizont stage of Theileria parva
 Unpublished.
 Position 1-814

Database Cross-references

UNILIB 27347; 10911.

Additional Information

Features

Key	Location	Qualifier	Value
source	1..814	db_xref	taxon:5875
		db_xref	UNILIB:27347
		mol_type	mRNA
		note	Vector: pCR4-TOPO; cDNA made using Clontech SMART system
		description	
		organism	Theileria parva
		strain	Muguga
		clone	TPFAN22
		clone_lib	TpMugugaSh01
		cell_line	F100TPM
		dev_stage	schizont

Sequence

Characteristics Length: 814 BP, A Count:281, C Count:105, G Count:173, T Count:255, Others Count:0
 Sequence

>emb1|BQ545112|BQ545112 EST628751 TpMugugaSh01 Theileria parva. cDNA c1
tgccggggttattataaatatttaaaataatcttgaatcagttggaaattcaaagtt
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attggaaaacaagtattccaaatccatgtaaatggaaagaagattatctaaatccaa
tttgcacaaacagatgaggacaatctacgaaaaaggagaagcctccggcacttcata
ggatgaacagtgtgaagaaaacgatccagatctaaaatccttgggagtaattttatagcc
gttaagttcaaaatgtttctgtttgaggatttcgggtgatgtatgtcgtaatttgct
atatttaattcactatcctaattgttttgc

Go to: General Description References Additional Cross-references Sequence

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